EXHIBIT #14

NOV 16 1995

SUMMARY OF SAFETY & EFFECTIVENESS
for
BIODEX SYSTEM 3

K951770

This device is designed for physical therapy to exercise, measure, evaluate and increas the strength of muscles and increase the Range of Motion (ROM) of joints. This device is a CLASS II Isokinetic Testing and Evaluation System, Classification #890.1925 and an AC Powered Goniometer, Classification #888.1240. Biodex Medical Systems has determined that this device is substantially equivalent to medical devices currently in commerce, Biodex System 2 Auto Program cleared via K-91 5648 and Biodex Clinical Data Station cleared via K-913021 and the Cybex 6000 cleared via K-905525.

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A determination of substantial equivalence is based upon:
1) The two cleared Biodex products combined are equivalent to the System 3 for their application and modes of operation.

2) The previous Biodex devices and System 3 use many of the same components. The software for the two devices are slight modifications of the same product.

3) The previous and new Biodex systems have the same fields of operation, except that one is an analog device and the other is a digital device.

4) The previous and new Biodex systems have the same safety requirements built into them.

5) The Cybex 6000 and Biodex System 3 are both digital designed products. The Cybex and Biodex are used for the same type of testing and rehabilitation.

6) This device is safe and effective for the application for which it is intended and has been tested to confirm its safety and effectiveness. Biodex Medical Systems continues to search appropriate sources for information relating to safety and effectiveness and maintains an in-house reporting system to identify adverse safety and effectiveness information.

I hereby certify that this Summary of Safety and Effectiveness applies for the above indicated device.

4/12/95
Date

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